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19 UNITED STATES DISTRICT COURT
20 SOUTHERN DISTRICT OF CALIFORNIA

21 IN RE INCRETIN-BASED
22 THERAPIES PRODUCTS LIABILITY
23 LITIGATION

24 As to All Related and Member Cases

MDL No. 2452

Magistrate: Mitchell D. Dembin
Judge: Anthony J. Battaglia

**DEFENDANT ELI LILLY AND
COMPANY'S OBJECTIONS
AND RESPONSES TO
PLAINTIFFS' SECOND SET OF
REQUESTS TO PRODUCE**

1 PROPOUNDING PARTY: Plaintiff

2 RESPONDING PARTY: Defendant Eli Lilly and Company

3 SET NUMBER: Second

4 Pursuant to Rule 34 of the Federal Rules of Civil Procedure, defendant
5 Eli Lilly and Company ("Lilly") hereby responds and objects to the Second Set of
6 Requests for Production of Documents and Tangible Things (the "Requests")
7 propounded by Plaintiffs as follows:

8 **PREFACE**

9 1. Lilly objects to each of these requests as unreasonably
10 burdensome in number, duplicative and cumulative of previously served requests,
11 and exceeding the limitations of Rule 26(b)(2). Plaintiffs have now served 114
12 interrogatories and 269 requests for production on Lilly (many of which contain
13 multiple discrete subparts). Plaintiffs have refused to agree to any reasonable limits
14 on the number of written discovery requests they may serve, and have advised Lilly
15 and the other defendants in this MDL that they plan to serve still more
16 interrogatories and requests for production. Lilly has already responded to 54
17 interrogatories and 85 requests for production, and has produced millions of pages
18 of documents and provided deposition testimony containing information responsive
19 to Plaintiffs' requests. Lilly has advised Plaintiffs of its objections to the number
20 of written discovery requests served, and requests a further meet and confer with
21 Plaintiffs regarding reasonable limits on the total number of interrogatories and
22 requests for production. Lilly therefore serves the following objections until the
23 parties are able to reach agreement on reasonable limits on written discovery,
24 and/or the Court is able to address the matter.

25 2. Lilly objects to Plaintiffs' "Definitions and Instructions" to the
26 extent they purport to impose any obligation on Lilly beyond the obligations
27 imposed by Rule 33 of the Federal Rules of Civil Procedure, or to alter the
28 commonly understood meaning of words or phrases.

1 3. All references to "Byetta" within Lilly's responses shall refer to
2 the twice daily injectable form of Byetta that was first approved by the FDA as safe
3 and effective on April 28, 2005.

4 4. All references to "Exenatide" (also known as "exendin-4") shall
5 refer to the 39-amino acid synthetic peptide that was originally identified in the
6 lizard *Heloderma suspectum* and is the active ingredient in Byetta.

7 5. Lilly co-promoted Byetta with Amylin pursuant to a
8 collaboration agreement in effect from September 2002 until November 2011.
9 Lilly objects to each request as overbroad to the extent it seeks information from
10 time periods not relevant to its co-promotion of Byetta.

11 6. Lilly objects to each of Plaintiffs' requests to the extent it seeks
12 information protected by the attorney-client privilege and/or attorney work product
13 doctrine, and will withhold such information.

14 7. Lilly objects to each of Plaintiffs' requests to the extent it seeks
15 information protected by HIPAA or other patient confidentiality laws or privileges.

16 8. Lilly objects to each of Plaintiffs' requests to the extent it seeks
17 confidential commercial information.

1 **OBJECTIONS AND RESPONSES**

2 **REQUEST NO. 1:**

3 Produce in electronic format complete copies of all Databases that
4 YOU use(d) to track, trend, or record information regarding any ADVERSE
5 EVENT that YOU associated with BYETTA, and attach source and other related
6 documentation. This request includes, to the extent that the databases incorporate
7 this information, any and all information regarding the nature and type of
8 ADVERSE EVENTS; when they were received by YOU; what action YOU took in
9 response to the ADVERSE EVENTS; who YOU contacted or communicated with
10 regarding the ADVERSE EVENTS; any follow-up efforts or investigation YOU
11 made to obtain further information regarding the ADVERSE EVENTS; if and
12 when YOU and the Food and Drug Administration ("FDA") communicated
13 regarding the ADVERSE EVENTS; whether the ADVERSE EVENT was in the
14 form of a Medwatch Report, communication from a medical provider or consumer,
15 an ADVERSE EVENT REPORT ("AER") or other form; what YOUR conclusions
16 were as to each ADVERSE EVENT; and the current status or final disposition of
17 the ADVERSE EVENT or REPORTABLE EVENT.

18 **RESPONSE:**

19 Lilly objects to this request as duplicative and cumulative of Plaintiffs'
20 prior written discovery, and as exceeding the limitations of Rule 26. To date,
21 Plaintiffs have served 269 requests for production (many of which contain multiple
22 discrete subparts) on Lilly. Plaintiffs have refused to agree to any limits on the
23 number of requests for production or other written discovery. Lilly therefore
24 objects to answering this request until the parties are able to agree on reasonable
25 limits, or the Court has an opportunity to address this issue. After this dispute is
26 resolved, Lilly anticipates serving amended objections and responses to this
27 request, or other discovery requests that Plaintiffs may serve in its place, consistent
28

1 with any agreement reached with Plaintiffs during the meet and confer process, or
2 as directed by the Court.

3 Lilly further objects to this request as overly broad, unduly
4 burdensome, and not reasonably calculated to lead to discovery of admissible
5 evidence, including to the extent it seeks information about adverse events
6 unrelated to the conditions at issue in this litigation, and to the extent it seeks
7 information from Lilly that is more readily available from Amylin, in light of the
8 termination of Lilly's collaboration agreement to co-promote Byetta with Amylin.
9 Lilly objects to this request to the extent it seeks confidential patient or reporter
10 information. Lilly also objects to this request to the extent it seeks information
11 protected by the attorney-client privilege or work product doctrine.

12 Without waiving the foregoing objections, Lilly responds that its JCCP
13 Production available to Plaintiffs includes a production of adverse drug reaction
14 ("ADR") reports from the Lilly Safety System ("LSS") in an electronic database
15 format. *See* LILLY00250453. Lilly further responds that information regarding
16 consumers in each reporting period for whom Lilly or Amylin received a report of
17 an alleged Byetta® associated adverse event can be found under Section 3 of the
18 Periodic Adverse Drug Experience Reports (PADERs) and Section 6 of the
19 Periodic Safety Update Reports (PSURs) within the Byetta® IND and NDA.

20 **REQUEST NO. 2:**

21 Produce copies of each file that YOU established and maintained in
22 response to each individual ADVERSE EVENT (commonly known as Adverse
23 Event Report event files, source files, backup files, or any other files containing
24 source documentation related to ADVERSE EVENTS) for BYETTA, including all
25 DOCUMENTS and ESI contained therein EVIDENCING or RELATING to any
26 and all information in YOUR possession, or references to information in YOUR
27 possession related to the underlying ADVERSE EVENT, including what attempts,
28 if any, YOU made to communicate with anyone, including, but not limited to health

1 care providers, consumers, sales reps or person/entity who reported the AER, to
2 gather further information regarding the ADVERSE EVENT, any analysis,
3 investigation, internal communications, follow-up efforts, or evaluation YOU
4 conducted, YOUR deliberations and decision-making processes used to determine
5 whether the ADVERSE EVENT was or was not a REPORTABLE EVENT, related
6 or unrelated, listed or not listed, associated or caused by BYETTA; any
7 investigations YOU conducted to determine the cause of the event, and copies of all
8 ADVERSE EVENT forms, including supplemental reports, MedWatch Reports,
9 and other information submitted to the Food and Drug Administration.

10 RESPONSE:

11 Lilly objects to this request as duplicative and cumulative of Plaintiffs'
12 prior written discovery, and as exceeding the limitations of Rule 26. To date,
13 Plaintiffs have served 269 requests for production (many of which contain multiple
14 discrete subparts) on Lilly. Plaintiffs have refused to agree to any limits on the
15 number of requests for production or other written discovery. Lilly therefore
16 objects to answering this request until the parties are able to agree on reasonable
17 limits, or the Court has an opportunity to address this issue. After this dispute is
18 resolved, Lilly anticipates serving amended objections and responses to this
19 request, or other discovery requests that Plaintiffs may serve in its place, consistent
20 with any agreement reached with Plaintiffs during the meet and confer process, or
21 as directed by the Court.

22 Lilly further objects to this request as overly broad, unduly
23 burdensome, and not reasonably calculated to lead to discovery of admissible
24 evidence, including on the ground that the terms "all documents," "any and all
25 information in your possession" and "references to information in your possession"
26 are overbroad; to the extent it seeks information about reported adverse events
27 unrelated to the conditions at issue in this litigation; and to the extent it seeks
28 discovery from Lilly that is more readily available from Amylin, in light of the

1 termination of Lilly's collaboration agreement to co-promote Byetta with Amylin.
2 Lilly objects to this request to the extent it seeks confidential patient or reporter
3 information. Lilly also objects to this request to the extent it seeks information
4 protected by the attorney-client privilege or work product doctrine.

5 Without waiving the foregoing objections, Lilly responds that its JCCP
6 Production available to Plaintiffs includes a production of adverse drug reaction
7 ("ADR") reports from the Lilly Safety System ("LSS") in an electronic database
8 format. See LILLY00250453. Lilly further responds that information regarding
9 consumers in each reporting period for whom Lilly or Amylin received a report of
10 an alleged Byetta® associated adverse event can be found under Section 3 of the
11 Periodic Adverse Drug Experience Reports (PADERs) and Section 6 of the
12 Periodic Safety Update Reports (PSURs) within the Byetta® IND and NDA.

13 **REQUEST NO. 3:**

14 To the extent not produced in response to the preceding request for
15 production, produce all DOCUMENTS AND ESI EVIDENCING and/or
16 RELATING to the following: any and all ADVERSE EVENTS YOU became
17 aware of for BYETTA, including what the ADVERSE EVENTS consisted of, and
18 when they were received b) YOU; what action YOU took, if any, in response to
19 each ADVERSE EVENT regarding BYETTA including any attempts to obtain
20 further information from the health care providers who treated the person whom
21 was allegedly injured by the drug; and communications YOU made or received
22 regarding each ADVERSE EVENT for BYETTA, including internal
23 communications; the results of any investigations regarding each ADVERSE
24 EVENT for BYETTA and/or the basis for the decision to not investigate; and what
25 YOUR conclusions were as to each ADVERSE EVENT; and the current status or
26 final disposition of the ADVERSE EVENT.

27 **RESPONSE:**

1 Lilly objects to this request as cumulative and duplicative of preceding
2 requests. Without waiving the foregoing objections, see Lilly's objections and
3 response to Request Nos. 1 and 2 above, which are incorporated as if fully set forth
4 here.

5 **REQUEST NO. 4:**

6 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING
7 to any ADVERSE EVENTS YOU received related to any PLAINTIFF in this
8 matter, including all DOCUMENTS and ESI EVIDENCING or RELATING to
9 what the ADVERSE EVENT consisted of; when it was received by YOU; what
10 action YOU took in response to the ADVERSE EVENT; any and all
11 communications YOU made or received regarding the ADVERSE EVENT,
12 including internal communications; any follow-up efforts YOU made to obtain
13 further information regarding the ADVERSE EVENT; whether and on what basis
14 YOU decided to not investigate; whether the ADVERSE EVENT was in the form
15 of a Medwatch Report, communication from a medical provider or consumer, an
16 Adverse Event Report or other form; what YOUR conclusions were as to the
17 ADVERSE EVENT; and the current status or final disposition of the ADVERSE
18 EVENT.

19 **RESPONSE:**

20 Lilly objects to this request as cumulative and duplicative of preceding
21 requests. Without waiving the foregoing objections, see Lilly's objections and
22 response to Request Nos. 1 and 2 above, which are incorporated as if fully set forth
23 here. Lilly further objects to this request to the extent it seeks information to be
24 provided through the Defendants' Fact Sheet procedure.

25 **REQUEST NO. 5:**

26 To the extent not produced in response to the preceding request for
27 production, produce all DOCUMENTS AND ESI EVIDENCING or RELATING
28

1 to the following information for each individual REPORTABLE EVENT for
2 BYETTA:

- 3 a. any information in YOUR possession or references to
4 information in YOUR possession related to the REPORTABLE
5 EVENT;
- 6 b. any attempts YOU made to communicate with anyone to gather
7 further information regarding the ADVERSE EVENT;
- 8 c. any communications YOU made or received, including internal
9 communications, regarding the REPORTABLE EVENT;
- 10 d. YOUR deliberations and decision-making processes used to
11 determine whether the ADVERSE EVENT was or was not a
12 REPORTABLE EVENT;
- 13 e. any investigations YOU conducted to determine the cause of the
14 event;
- 15 f. any action YOU took as a result of the REPORTABLE EVENT
16 to prevent recurrence of the REPORTABLE EVENT;
- 17 g. experts and/or consultants whom YOU contacted regarding the
18 ADVERSE EVENT;
- 19 h. copies of all adverse event report forms, including supplemental
20 reports, and other information submitted to the FDA;
- 21 i. analysis of nature, severity and frequency of the ADVERSE
22 EVENT;
- 23 j. reporting rates analysis and trending of the ADVERSE EVENT.

22 RESPONSE:

23 Lilly objects to this request as cumulative and duplicative of preceding
24 requests. Without waiving the foregoing objections, see Lilly's objections and
25 response to Request Nos. 1, 2 and 4 above, which are incorporated as if fully set
26 forth here.

1 **REQUEST NO. 6:**

2 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING
3 to any request by the Food and Drug Administration for YOU to conduct post-
4 market surveillance of BYETTA; and any plans, reports, or other information YOU
5 submitted to the Food and Drug Administration in response.

6 **RESPONSE:**

7 Lilly objects to this request as duplicative and cumulative of Plaintiffs'
8 prior written discovery, and as exceeding the limitations of Rule 26. To date,
9 Plaintiffs have served 269 requests for production (many of which contain multiple
10 discrete subparts) on Lilly. Plaintiffs have refused to agree to any limits on the
11 number of requests for production or other written discovery. Lilly therefore
12 objects to answering this request until the parties are able to agree on reasonable
13 limits, or the Court has an opportunity to address this issue. After this dispute is
14 resolved, Lilly anticipates serving amended objections and responses to this
15 request, or other discovery requests that Plaintiffs may serve in its place, consistent
16 with any agreement reached with Plaintiffs during the meet and confer process, or
17 as directed by the Court.

18 Lilly further objects to this request on the ground that the terms "all
19 documents and ESI" and "any request" are overly broad and unduly burdensome.
20 Lilly objects to this request as not reasonably calculated to lead to discovery of
21 admissible evidence to the extent it seeks information about documents unrelated to
22 the conditions at issue in this litigation. Lilly objects to this request to the extent it
23 seeks confidential patient or reporter information. Lilly also objects to this request
24 to the extent it seeks information protected by the attorney-client privilege or work
25 product doctrine.

26 Without waiving the foregoing objections, Lilly responds that both the
27 IND and NDA for Byetta® were submitted to the FDA, and further directs Plaintiff
28

1 to BY00390802-BY00403814 and BY00416353-BY00426172, which contain
2 communications with the FDA.

3 **REQUEST NO. 7:**

4 Produce all DOCUMENTS AND ESI EVIDENCING or referring to
5 any and all data analysis or trends of adverse events that were reported to, or
6 conducted by, YOU regarding BYETTA, including any studies, research or
7 documents prepared to reflect any analysis or trend.

8 **RESPONSE:**

9 Lilly objects to this request as duplicative and cumulative of Plaintiffs'
10 prior written discovery, and as exceeding the limitations of Rule 26. To date,
11 Plaintiffs have served 269 requests for production (many of which contain multiple
12 discrete subparts) on Lilly. Plaintiffs have refused to agree to any limits on the
13 number of requests for production or other written discovery. Lilly therefore
14 objects to answering this request until the parties are able to agree on reasonable
15 limits, or the Court has an opportunity to address this issue. After this dispute is
16 resolved, Lilly anticipates serving amended objections and responses to this
17 request, or other discovery requests that Plaintiffs may serve in its place, consistent
18 with any agreement reached with Plaintiffs during the meet and confer process, or
19 as directed by the Court.

20 Lilly further objects to this request on the ground that the terms "all
21 documents and ESI" and "any and all data analysis or trends" are overly broad and
22 unduly burdensome. Lilly objects to this request as not reasonably calculated to
23 lead to discovery of admissible evidence to the extent it seeks information about
24 documents unrelated to the conditions at issue in this litigation. Lilly objects to this
25 request to the extent it seeks confidential patient or reporter information. Lilly also
26 objects to this request to the extent it seeks information protected by the attorney-
27 client privilege or work product doctrine.

1 **REQUEST NO. 8:**

2 Produce all DOCUMENTS AND ESI EVIDENCING or referring to
3 any and all written policies, procedures or standard operating procedures YOU had
4 in place at the time YOU first began to market or distribute BYETTA regarding
5 receiving, reviewing, investigating, evaluating, and/or documenting ADVERSE
6 EVENTS YOU received for drugs that YOU marketed or distributed, including
7 BYETTA. This includes for example, any questionnaires or follow-up procedure
8 YOU developed to deal with specific types of injuries related to BYETTA such as,
9 but not limited to, pancreatitis, pancreatic and thyroid cancers.

10 **RESPONSE:**

11 Lilly objects to this request as duplicative and cumulative of Plaintiffs'
12 prior written discovery, and as exceeding the limitations of Rule 26. To date,
13 Plaintiffs have served 269 requests for production (many of which contain multiple
14 discrete subparts) on Lilly. Plaintiffs have refused to agree to any limits on the
15 number of requests for production or other written discovery. Lilly therefore
16 objects to answering this request until the parties are able to agree on reasonable
17 limits, or the Court has an opportunity to address this issue. After this dispute is
18 resolved, Lilly anticipates serving amended objections and responses to this
19 request, or other discovery requests that Plaintiffs may serve in its place, consistent
20 with any agreement reached with Plaintiffs during the meet and confer process, or
21 as directed by the Court.

22 Lilly further objects to this request on the ground that the terms "all
23 documents and ESI," "all written policies, procedures, or standard operating
24 procedures" are overly broad and unduly burdensome. Lilly has had numerous
25 policies and procedures over the period at issue that relate, to varying degrees, to
26 the collection, processing and reporting of adverse event reports for Byetta®, many
27 of which have at best only marginal relevance to the disputed issues in this
28 litigation and for which the burden of identification, collection and production

1 would outweigh any benefit. Lilly objects to this request as misdirected to it to the
2 extent it seeks materials regarding activities not performed by Lilly following the
3 termination of its collaboration agreement with Amylin in November 2011. Lilly
4 further objects to this request to the extent it seeks information protected by the
5 attorney-client privilege or work product doctrine.

6 Without waiving the foregoing objections, Lilly directs Plaintiff to the
7 procedures at LILLY00000214-LILLY00000463.

8
9 **REQUEST NO. 9:**

10 Produce all DOCUMENTS AND ESI EVIDENCING any and all
11 written policies, procedures, or standard operating procedures YOU had in place
12 during the entire period of time since BYETTA was first marketed anywhere
13 regarding the timely identification, communication, investigation, and evaluation of
14 ADVERSE EVENTS that may constitute REPORTABLE EVENTS; the review
15 process for determining when an ADVERSE EVENT meets the criteria for being a
16 REPORTABLE EVENT; the documentation and recordkeeping requirements for
17 information YOU evaluated to determine whether ADVERSE EVENTS YOU
18 received constituted REPORTABLE EVENTS, the documentation and
19 recordkeeping requirements for all REPORTABLE EVENTS and information
20 related thereto actually submitted to the FDA; and the documentation and
21 recordkeeping requirements regarding any information that was evaluated for the
22 purpose of preparing the submission of annual reports, PADERs and PSURs.

23 **RESPONSE:**

24 Lilly objects to this request as duplicative and cumulative of Plaintiffs'
25 prior written discovery, and as exceeding the limitations of Rule 26. To date,
26 Plaintiffs have served 269 requests for production (many of which contain multiple
27 discrete subparts) on Lilly. Plaintiffs have refused to agree to any limits on the
28 number of requests for production or other written discovery. Lilly therefore

1 objects to answering this request until the parties are able to agree on reasonable
2 limits, or the Court has an opportunity to address this issue. After this dispute is
3 resolved, Lilly anticipates serving amended objections and responses to this
4 request, or other discovery requests that Plaintiffs may serve in its place, consistent
5 with any agreement reached with Plaintiffs during the meet and confer process, or
6 as directed by the Court.

7 Lilly further objects to this request on the ground that the terms “all
8 documents and ESI” and “all written policies” are overly broad and unduly
9 burdensome. Lilly has had numerous policies and procedures over the period at
10 issue that relate, to varying degrees, to the collection, processing and reporting of
11 adverse event reports for Byetta®, many of which have at best only marginal
12 relevance to the disputed issues in this litigation and for which the burden of
13 identification, collection and production would outweigh any benefit. Lilly objects
14 to this request as misdirected to it to the extent it seeks materials regarding
15 activities not performed by Lilly following the termination of its collaboration
16 agreement with Amylin in November 2011. Lilly objects to this request to the
17 extent that it seeks documents that pertain solely to locations outside the United
18 States. Lilly objects to this request to the extent it seeks information protected by
19 the attorney-client privilege or work product doctrine.

20 Without waiving the foregoing objections, Lilly directs Plaintiffs to the
21 procedures at LILLY00000214-LILLY00000463.

22
23 **REQUEST NO. 10:**

24 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING
25 to any and/or all changes or additions YOU made to the procedures and standards
26 identified in the preceding request for production from January 2003 through the
27 present.
28

1 RESPONSE:

2 Lilly objects to this request as duplicative and cumulative of Plaintiffs'
3 prior written discovery, and as exceeding the limitations of Rule 26. To date,
4 Plaintiffs have served 269 requests for production (many of which contain multiple
5 discrete subparts) on Lilly. Plaintiffs have refused to agree to any limits on the
6 number of requests for production or other written discovery. Lilly therefore
7 objects to answering this request until the parties are able to agree on reasonable
8 limits, or the Court has an opportunity to address this issue. After this dispute is
9 resolved, Lilly anticipates serving amended objections and responses to this
10 request, or other discovery requests that Plaintiffs may serve in its place, consistent
11 with any agreement reached with Plaintiffs during the meet and confer process, or
12 as directed by the Court.

13 Lilly further objects to this request on the ground that the terms "all
14 documents and ESI" and "any and/or all changes or additions" are overly broad
15 and unduly burdensome. Lilly has had numerous policies and procedures over the
16 period at issue that relate, to varying degrees, to the collection, processing and
17 reporting of adverse event reports for Byetta®, many of which have at best only
18 marginal relevance to the disputed issues in this litigation and for which the burden
19 of identification, collection and production would outweigh any benefit. Lilly
20 objects to this request as misdirected to it to the extent it seeks materials regarding
21 activities not performed by Lilly following the termination of its collaboration
22 agreement with Amylin in November 2011. Lilly objects to this request to the
23 extent it seeks information protected by the attorney-client privilege or work
24 product doctrine.

25 Without waiving the foregoing objections, Lilly directs Plaintiffs to the
26 procedures at LILLY00000214-LILLY00000463.

1 **REQUEST NO. 11:**

2 To the extent not already produced, produce all DOCUMENTS AND
3 ESI EVIDENCING or referring to any information provided to any of YOUR
4 employees or agents who were responsible for following up with or communicating
5 with health care providers regarding adverse events associated with BYETTA
6 regarding the following: the potential for BYETTA to cause pancreatitis, pancreatic
7 and/or thyroid cancer, any information that these persons were to communicate to
8 and/or obtain from the health care provider(s), and any training materials, scripts,
9 questionnaires, and instructions that were to guide interactions with health care
10 providers regarding adverse events for BYETTA.

11 **RESPONSE:**

12 Lilly objects to this request as duplicative and cumulative of Plaintiffs'
13 prior written discovery, and as exceeding the limitations of Rule 26. To date,
14 Plaintiffs have served 269 requests for production (many of which contain multiple
15 discrete subparts) on Lilly. Plaintiffs have refused to agree to any limits on the
16 number of requests for production or other written discovery. Lilly therefore
17 objects to answering this request until the parties are able to agree on reasonable
18 limits, or the Court has an opportunity to address this issue. After this dispute is
19 resolved, Lilly anticipates serving amended objections and responses to this
20 request, or other discovery requests that Plaintiffs may serve in its place, consistent
21 with any agreement reached with Plaintiffs during the meet and confer process, or
22 as directed by the Court.

23 Lilly further objects to this request on the ground that the terms "all
24 documents and ESI," "any information," and "any of YOUR employees or agents"
25 are overly broad and unduly burdensome. Lilly objects to this request to the extent
26 it seeks confidential patient or reporter information. Lilly objects to this request as
27 misdirected to it to the extent it seeks materials regarding activities not performed
28 by Lilly following the termination of its collaboration agreement with Amylin in

1 November 2011. Lilly objects to this request to the extent it seeks information
2 protected by the attorney-client privilege or work product doctrine. Lilly objects to
3 this request as cumulative and duplicative of preceding requests.

4 Without waiving the foregoing objections, see Lilly's objections and
5 response to Request Nos. 1 and 2 above, which are incorporated as if fully set forth
6 here.

7
8 **REQUEST NO. 12:**

9 Produce all DOCUMENTS AND ESI EVIDENCING any and/or all
10 written policies, procedures or standard operating procedures YOU had in place
11 during the entire period of time since BYETTA was first marketed anywhere
12 regarding establishing and maintaining files for each ADVERSE EVENT that
13 would contain any and/or all information in YOUR possession or references to
14 information in YOUR possession related to the underlying ADVERSE EVENT,
15 including all documentation of YOUR deliberations and decision-making processes
16 used to determine if a drug-related death, serious injury, or injury of special interest
17 was or was not a REPORTABLE EVENT, and copies of all adverse event report
18 forms and other information submitted to the FDA.

19 **RESPONSE:**

20 Lilly objects to this request as duplicative and cumulative of Plaintiffs'
21 prior written discovery, and as exceeding the limitations of Rule 26. To date,
22 Plaintiffs have served 269 requests for production (many of which contain multiple
23 discrete subparts) on Lilly. Plaintiffs have refused to agree to any limits on the
24 number of requests for production or other written discovery. Lilly therefore
25 objects to answering this request until the parties are able to agree on reasonable
26 limits, or the Court has an opportunity to address this issue. After this dispute is
27 resolved, Lilly anticipates serving amended objections and responses to this
28 request, or other discovery requests that Plaintiffs may serve in its place, consistent

1 with any agreement reached with Plaintiffs during the meet and confer process, or
2 as directed by the Court. Lilly objects to this request as cumulative and duplicative
3 of preceding requests.

4 Without waiving the foregoing objections, see Lilly's objections and
5 response to Request Nos. 1, 2, 8, 9, and 10 above, which are incorporated as if fully
6 set forth here.

7
8 **REQUEST NO. 13:**

9 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING
10 to any and/or all changes or additions YOU made to the procedures and standards
11 identified in the preceding request for production during the entire period of time
12 since BYETTA was first marketed anywhere.

13 **RESPONSE:**

14 Lilly objects to this request as duplicative and cumulative of Plaintiffs'
15 prior written discovery, and as exceeding the limitations of Rule 26. To date,
16 Plaintiffs have served 269 requests for production (many of which contain multiple
17 discrete subparts) on Lilly. Plaintiffs have refused to agree to any limits on the
18 number of requests for production or other written discovery. Lilly therefore
19 objects to answering this request until the parties are able to agree on reasonable
20 limits, or the Court has an opportunity to address this issue. After this dispute is
21 resolved, Lilly anticipates serving amended objections and responses to this
22 request, or other discovery requests that Plaintiffs may serve in its place, consistent
23 with any agreement reached with Plaintiffs during the meet and confer process, or
24 as directed by the Court. Lilly objects to this request as cumulative and
25 duplicative of preceding requests.

26 Without waiving the foregoing objections, see Lilly's objections and
27 response to Request Nos. 1, 2, 8, 9, and 10 above, which are incorporated as if fully
28 set forth here.

1 **REQUEST NO. 14:**

2 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING
3 to communications and/or correspondence known as "Dear Doctor" or "Dear
4 Healthcare Professional" letters prepared, generated, authored, and/or sent by YOU
5 to health care professionals, including physicians, hospitals, pharmacies and clinics,
6 in the United States and other countries, including any and all preliminary and final
7 drafts of such letters, all minutes from company, departmental or directors meetings
8 in which revisions or amendments to such communications and letters were
9 discussed, as well as all editions or notations made by YOU, concerning BYETTA.

10 **RESPONSE:**

11 Lilly objects to this request as duplicative and cumulative of Plaintiffs'
12 prior written discovery, and as exceeding the limitations of Rule 26. To date,
13 Plaintiffs have served 269 requests for production (many of which contain multiple
14 discrete subparts) on Lilly. Plaintiffs have refused to agree to any limits on the
15 number of requests for production or other written discovery. Lilly therefore
16 objects to answering this request until the parties are able to agree on reasonable
17 limits, or the Court has an opportunity to address this issue. After this dispute is
18 resolved, Lilly anticipates serving amended objections and responses to this
19 request, or other discovery requests that Plaintiffs may serve in its place, consistent
20 with any agreement reached with Plaintiffs during the meet and confer process, or
21 as directed by the Court.

22 Lilly further objects to this request on the ground that the terms "all
23 documents and ESI," "any and all preliminary and final drafts," "all minutes," and
24 "all editions or notations" are overly broad and unduly burdensome. Lilly objects
25 to this request as overbroad, unduly burdensome, and not reasonably calculated to
26 lead to discovery of admissible evidence to the extent that it seeks information
27 concerning "Dear Doctor" or "Dear Healthcare Provider Letters" disseminated to
28 locations outside the United States, or seeks documents that were not seen by

1 Plaintiffs' prescribing physicians. Lilly further objects to this request on the ground
2 that it seeks information protected by the attorney-client privilege and work product
3 doctrine.

4 Without waiving the foregoing objections, Lilly responds that copies
5 of letters it has sent to healthcare providers in the United States are contained in the
6 Byetta® IND/NDA. Lilly further objects to this request to the extent it seeks
7 information to be provided through the Defendants' Fact Sheet procedure.

8
9 **REQUEST NO. 15:**

10 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING
11 to the organization of any division, segment, or office of DEFENDANT that
12 participates in the receipt, collection, evaluation, analysis, trending, and/or
13 reporting of information to any regulatory agency regarding ADVERSE EVENTS
14 regarding BYETTA.

15 **RESPONSE:**

16 Lilly objects to this request as duplicative and cumulative of Plaintiffs'
17 prior written discovery, and as exceeding the limitations of Rule 26. To date,
18 Plaintiffs have served 269 requests for production (many of which contain multiple
19 discrete subparts) on Lilly. Plaintiffs have refused to agree to any limits on the
20 number of requests for production or other written discovery. Lilly therefore
21 objects to answering this request until the parties are able to agree on reasonable
22 limits, or the Court has an opportunity to address this issue. After this dispute is
23 resolved, Lilly anticipates serving amended objections and responses to this
24 request, or other discovery requests that Plaintiffs may serve in its place, consistent
25 with any agreement reached with Plaintiffs during the meet and confer process, or
26 as directed by the Court.

27 Without waiving the foregoing objections, Lilly directs Plaintiff to its
28 production of corporate organization charts at LILLY00000001-LILLY00000006.

1 **REQUEST NO. 16:**

2 Produce all DOCUMENTS AND ESI EVIDENCING or RELATING
3 to entities with whom YOU contract regarding the collection, processing,
4 evaluating, investigation, follow-up, analysis, reporting and/or publication of
5 ADVERSE EVENTS for BYETTA including but not limited to Functional Service
6 Providers, Contract Research Organizations, vendors, and/or consultants.

7 **RESPONSE:**

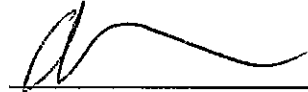
8 Lilly objects to this request as duplicative and cumulative of Plaintiffs'
9 prior written discovery, and as exceeding the limitations of Rule 26. To date,
10 Plaintiffs have served 269 requests for production (many of which contain multiple
11 discrete subparts) on Lilly. Plaintiffs have refused to agree to any limits on the
12 number of requests for production or other written discovery. Lilly therefore
13 objects to answering this request until the parties are able to agree on reasonable
14 limits, or the Court has an opportunity to address this issue. After this dispute is
15 resolved, Lilly anticipates serving amended objections and responses to this
16 request, or other discovery requests that Plaintiffs may serve in its place, consistent
17 with any agreement reached with Plaintiffs during the meet and confer process, or
18 as directed by the Court. Lilly further objects to this request as cumulative and
19 duplicative of preceding requests.

20 Without waiving the foregoing objections, see Lilly's objections and
21 response to Request Nos. 1, 2, 8, 9, and 10 above, which are incorporated as if fully
22 set forth here.

1 DATED: January 16, 2014

PEPPER HAMILTON LLP

2 By:



3 Allan A. Thoen

4 Attorney for Defendant

5 Eli Lilly and Company

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I am a resident of or employed in the county where the service described below occurred. My business address is 3000 Two Logan Square, Philadelphia, PA 19103. I am familiar with this firm's practice for collection and processing of correspondence for mailing with the United States Postal service. In the ordinary course of business, correspondence collected from me would be processed on the same day, with postage thereon fully prepaid and placed for deposit that day with the United States Postal Service.

Defendant Eli Lilly and Company's Objections and Responses to Plaintiffs' First Set of Requests to Produce

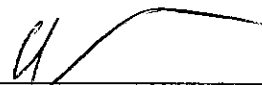
by putting a true and correct copy thereof in a sealed envelope, with postage fully prepaid, and placing the envelope for collection and mailing today with the United States Postal Service in accordance with the firm's ordinary business practice, and/or by electronic mail, addressed as follows:

Ryan L. Thompson
Watts Guerra LLP
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1 Hunter J. Shkolnik
2 Napoli, Bern, Ripka
3 & Shkolnik LLP
4 350 Fifth Avenue
5 New York, NY 10018
6 Hunter@NapoliBern.com
7 *Served by Email*

8 I hereby certify that a copy of the above and foregoing has been mailed and/or sent
9 by electronic mail to the following counsel of record for all of the actions that will
10 be affected on January 16, 2014.

11 
12 _____
13 Allan A. Thoen
14 Attorney for Defendant
15 Eli Lilly and Company
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